

## Attachment C

### Focus Area C - Laboratory Capacity - Biologic Agents

Focus Area C includes two Critical Capacities:

- A. Laboratory Services
- B. Laboratory Infrastructure

Each Focus Area includes Critical Capacities, which are the core expertise and infrastructure that should be implemented as soon as possible to enable a public health system to prepare for and respond to bioterrorism, other infectious disease outbreaks, and other public health threats and emergencies. Some of the Critical Capacities include Critical Benchmarks, which recipients are required to complete prior to submission of the work plan (see Notice of Cooperative Agreement Award). Further, some Critical Capacities have associated with them Activities That May be Considered. Though not exhaustive, these lists provide examples of related activities that applicants may propose to develop to augment the relevant Critical Capacity.

For each Critical Capacity, the work plan must provide: (a) a brief description of the existing capacity in your jurisdiction, (b) an assessment of whether this capacity is adequate, and (c) where you judge the capacity inadequate, a proposal for effecting improvements during this budget period--including a timeline to guide implementation, measurable milestones to facilitate accountability, and a proposed budget. This document should not exceed 5 pages.

Some Focus Areas also include Enhanced Capacities, which are the additional expertise and infrastructure--i.e., over and beyond the Critical Capacities--to enable public health systems to have optimal capacities to respond to bioterrorism, other infectious disease outbreaks, and other public health threats and emergencies. Enhanced Capacities should be addressed only after Critical Capacities have been achieved or are well along in development. Recipients are encouraged to choose among these suggested activities or propose other comparable ones.

For each Enhanced Capacity that the recipient chooses to address now, the work plan must include a brief proposal for effecting the intended enhancements during this budget period--including a timeline to guide implementation, measurable milestones to

facilitate accountability, and a proposed budget. This document is not to exceed 5 pages

**Recipient Activities:**

- A. CRITICAL CAPACITY: to develop and implement a jurisdiction-wide program to provide rapid and effective laboratory services in support of the response to bioterrorism, other infectious disease outbreaks, and other public health threats and emergencies.
1. Prepare a timeline for the development of a plan to improve working relationships and communication between Level A (clinical) laboratories and Level B/C Laboratory Response Network laboratories to ensure that Level A laboratories maintain core capability to: (a) perform rule-out testing on critical BT agents; (b) safely package and handle specimens; and (c) refer to higher level laboratories for further testing.  
**(CRITICAL BENCHMARK #10)**
  2. Develop an integrated response plan that directs how the laboratories within your jurisdiction will respond to a bioterrorism incident to include: (a) roles and responsibilities; (b) inter- and intra-jurisdictional surge capacity; (c) how the plan integrates with other department-wide emergency response efforts; (d) protocols for safe transport of specimens by air and ground; and (e) how lab results will be reported and shared with local public health and law enforcement agencies. **(LINK WITH FOCUS AREAS A, B, AND F)**
  3. Establish operational relationships with local members of HazMat teams, first responders, and FBI to provide laboratory support for their response to bioterrorism, including environmental testing and chain-of-custody procedures. Enhance these relationships through establishment of designated points of contact, cross-training in each discipline, and/or joint sponsorship of conferences, for example.
  4. Enhance relationships with community laboratory practitioners, university laboratories, and infectious disease physicians through participation in infectious disease rounds and conferences.
- B. CRITICAL CAPACITY, as a member of the Laboratory Response Network (LRN), to ensure adequate and secure laboratory facilities, reagents, and equipment to rapidly detect and correctly identify biological agents likely to be used in a bioterrorist incident.
1. Develop operational plans and protocols that include: (a) specimen/samples transport and handling; (b) worker safety; (c) appropriate Bio-Safety Level

(BSL) working conditions for each threat agent; (d) staffing and training of personnel; (e) quality control and assurance (adherence to and validation of laboratory methods and protocols); (f) internal and external proficiency testing; (g) triage procedure for prioritizing intake and testing of specimens/samples before analysis; (h) secure storage of critical agents; and (i) appropriate levels of supplies and equipment needed to respond to disease outbreaks or bioterrorism events with a strong emphasis on surge capacities needed to effectively respond to a bioterrorism incident.

2. Ensure capacity exists for LRN-validated testing of the following BT threat agents on the Category A list:
  - A. *Bacillus anthracis*
  - B. *Yersinia pestis*
  - C. *Francisella tularensis*
  - D. *Clostridium botulinum* toxin
  - E. Other Level B and C protocols as they are approved.
3. Ensure at least one public health laboratory in your jurisdiction has the appropriate instrumentation and appropriately trained staff to perform CDC-developed real-time polymerase chain reaction (PCR) and time-resolved fluorescence (TRF) rapid assays. Integrate new advanced rapid identification methods into the current laboratory testing algorithm. Contact CDC technical support staff for further information on approved equipment as necessary.
4. Conduct at least one simulation exercise per year that specifically tests laboratory readiness and capability to detect and identify at least one BT threat agent on the Category A list.
5. Ensure at least one operational Bio-Safety Level 3 (BSL-3) facility in your jurisdiction. If not immediately possible, BSL-3 practices, as outlined in the CDC-NIH publication “Bio-safety in Microbiological and Biomedical Laboratories, 4<sup>th</sup> Edition” (BMBL), should be used (see [www.cdc.gov/od/ohs](http://www.cdc.gov/od/ohs)).
6. Ensure that laboratory security is consistent, at a minimum with the guidelines set forth in BMBL appendix F and any subsequent updates. Enhance laboratory security as needed through use of measures such as (a) video surveillance; (b) perimeter security; and (c) screening for radiological, explosive, and chemical risk of specimens prior to biological analysis or others. Pursuant to 18 USC section 175b, as added by section 817 of the USA PATRIOT Act of 2001, P.L. 107-56, aliens (other than aliens lawfully admitted to the United States for permanent residence) are prohibited from possessing

select agents if they are nationals of countries as to which the Secretary of State (pursuant to provisions of the Export Administration Act of 1979, the Foreign Assistance Act of 1981, or the Arms Export Control Act) has made an unrevoked determination that such countries have repeatedly provided support for acts of international terrorism.

7. Enhance electronic communications within the LRN to enable network capacity monitoring, BT sentinel surveillance, support of proficiency-testing, multi-center validation studies for new methods, and support for future LRN site enhancements; laboratories should have appropriate computer equipment and high-speed Internet connectivity to access the LRN's protocols, reagents, and lab user applications. **(LINK WITH FOCUS AREA E)**

#### **CDC Activities:**

- A. Develop and disseminate updated threat agent priority lists and laboratory recommendations appropriate to evolving conditions.
- B. Develop and/or identify advanced methods and new LRN diagnostic technologies for identification of biological threat agents. Transfer this technology as appropriate to LRN member laboratories.
- C. Facilitate availability and access to critical reagents that have been properly evaluated to ensure consistent quality and comparability of results between laboratories and that meet regulatory requirements for intended use.
- D. Provide consultation, assistance, and training relative to scientific expertise, appropriate methods, specialized techniques, and operational management.
- E. Assist in the development of quality assurance standards that ensure proper chain of custody, adequate security, transport, and storage of specimens, secure and effective communication of laboratory results, and acceptable performance in an external proficiency testing program. Coordinate the development and implementation of a proficiency testing program.
- F. Conduct evaluations and determine that public health laboratories meet the core capacity and capability requirements to respond to biological terrorism.
- G. Assist in monitoring and evaluating scientific and operational accomplishments and progress in achieving the purpose of this program.

- H. Assist in further developing and implementing a national network that will provide access for all public health laboratories to advanced capacity and confirmatory testing for the priority biologic threat agents. Assist in planning and participate in periodic planning/coordination meetings.
- I. Develop and disseminate CDC protocols for collecting blood and urine specimens and transporting to public health laboratories for analysis.